

REMARKS

Claims 1, 7-14, 18, and 19 are pending in this application. Claim 18 was rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 8, and 10 were rejected under 35 U.S.C. § 102(a). Claims 1, 7-14, 18, and 19 were variously rejected under 35 U.S.C. § 103.

By this amendment, claim 1 has been amended and new claim 21 has been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification, for example, at page 4, lines 4-6, and at page 6, lines 9-14. Support for new claim 21 is found, *inter alia*, at page 4, lines 12-14.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Information Disclosure Statement

Although an information disclosure statement was properly filed November 24, 2003, the Examiner indicates that the non-US documents have not been considered. Accordingly, submitted herewith is a copy of the documents in the original November 24, 2003 information disclosure statement filing and a copy of the non-US documents listed therein, with the exception of those cited on form PTO-892.

Applicants respectfully request consideration of these references.

Objection to drawings

The drawings were objected to as failing to comply with 37 CFR 1.84. Submitted herewith are corrected drawing.

Rejection under 35 U.S.C. §112, second paragraph

Claim 18 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that there is no “recitation or description or listing of what “emulsion forming agent” is included in the carrier composition” of claim 18. Office Action, page 3. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the term “emulsion forming agents” is understood by those of skill in the art. Emulsion forming agents are also well-known to those of skill in the art. The specification describes agents for forming emulsion, for example, at column 23, lines 43-45, column 32, line 64, to column 33, line 2. Emulsion forming agents are also described in U.S. Pat. No. 5,616,342 to Lyons, for example, at column 2, lines 38-46, and column 8, lines 1-16. Applicants respectfully submit that the term “emulsion forming agents” does not render claim 18 indefinite.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §102

Claims 1, 8, and 10 were rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Rajagopalan, *et al.* (WO 99/51284; “Rajagopalan”). Applicants respectfully traverse this rejection.

Without acquiescing to this rejection, claim 1 has been amended to recite that the “photosensitizer carrier composition is in a solid form.” Support for this language is expressly provided at least at page 4, lines 4-6, and at page 6, lines 9-10, of the instant specification. As noted

by the Examiner at page 4 of the Office Action, Rajagopalan describes compositions in a liquid form. Thus, the solid form of the claimed composition is distinct from that described in Rajagopalan.

Since Rajagopalan does not teach each and every element of the claimed invention, Rajagopalan does not anticipate claim 1, nor claims 8 and 10 which depend from claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(a).

Rejection under 35 U.S.C. §103

Claims 1, 7-14, 18 and 19 were variously rejected under 35 U.S.C. §103 as allegedly unpatentable over Lyons (U.S. Pat. No. 5,616,342). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established.

As noted above, the claimed invention is directed to photosensitizer carrier composition in a solid form. Lyons is directed to liquid emulsions containing a photosensitizer. Lyons provides no teaching or suggestion that the emulsions taught therein be converted to a solid form. Further, Lyons provides no motivation for the skilled artisan to modify the teachings to produce a solid form composition as claimed. In fact, Lyons teaches away from any need to generate a solid form

composition when it draws a distinction between the storage stability of the emulsions taught therein and the relative instability of prior art liposomal formulations unless lyophilized.¹

Thus, Applicants respectfully submit that a *prima facie* case of obvious has not been established with regard to claims 1 and 7-14.

With respect to claims 18 and 19, Applicants submit that no *prima facie* case of obviousness has been presented. Lyons fails to teach, suggest, or otherwise indicate the use of poloxamer 188 with a photosensitizer. It is well established law that the disclosure of a genus, such as poloxamers in general, does not necessarily render all possible species obvious (see MPEP 2144.08, especially 2144.08 II and the case law cited therein). The establishment of a *prima facie* case of obviousness in such an instance requires the determination of motivation to select the particular species claimed. Mere assertion that the genus of poloxamers includes poloxamer 188 is insufficient to establish such a motivation. Similarly, there is no burden on Applicants to demonstrate that poloxamer 188 would not work prior to the establishment of a *prima facie* case based upon a motivation by the artisan of ordinary skill to use poloxamer 188 when it is not expressly taught or suggested by Lyons. It is simply not the burden upon Applicants to show the “criticality of excluding poloxamer 188” without establishment of a *prima facie* case.

In sum, Applicants respectfully submit that a *prima facie* case of obvious has not been made with respect to the pending claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

¹ See, for example, Lyons, column 2, lines 59-61, and column 3, lines 1-2.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 273012011601. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 26, 2005

Respectfully submitted,

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